Rec'd PCT/PTO 05 NOV 1997

FORM PTO-1390 (REV 10-96) — U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
3000	08/981,665 08/613,487

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US 97/03347	11 March 1997	11 March 1996

TITLE OF INVENTION: DEVICE FOR THE COLLECTION, TESTING AND SHIPMENT OF BODY FLUID SAMPLES

APPLICANT(S) FOR DO/EO/US: Stan Cipkowski

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [ ] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [ ] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [X] is not required, as the application was filed in the United States Receiving Office (RO/US)
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2))
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [X] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [ ] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    International Search Report
    Small Entity Declaration
    PCT Request

U S APPLICATION NO (if known, see 37 CFR 1 5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
08/613,487	PCT/US97/03347	3000

17 [X] The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
Search Report has been prepared by the EPO or JPO	**$910.00**	
International preliminary examination fee paid to USPTO (37 CFR 1.482)	**$700.00**	
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2))	**$770.00**	
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO	**$1040.00**	
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4)	**$96.00**	

ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 930.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1 492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	15 - 20 =	--	X **$22.00**	$	
Independent claims	3 - 3 =	--	X **$80.00**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$260.00**	$	
TOTAL OF ABOVE CALCULATIONS =				$ 930.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$ 465.00	
Processing fee of **$130.00** for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
TOTAL NATIONAL FEE =				$ 465.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$ 40.00	
TOTAL FEES ENCLOSED =				$ 505.00	
				Amount to be: refunded	$
				charged	$

a. [X] A check in the amount of $ 505.00 to cover the above fees is enclosed.

b. [ ] Please charge my Deposit Account No _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [ ] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO

Edmund M. Jaskiewicz
1730 M Street NW Ste. 400
Washington, D.C. 20036

Tel: (202) 296-2900

SIGNATURE

Edmund M. Jaskiewicz
NAME

17875
REGISTRATION NUMBER

11/05/97

DEVICE FOR THE COLLECTION, TESTING AND SHIPMENT OF BODY FLUID SAMPLES

RELATED APPLICATIONS

For purposes of the United States of America, this is a continuation-in-part application of United States Patent Application Serial No. 08/613,487 filed March 11, 1996.

TECHNICAL FIELD

The present invention relates to a test kit for the collection and testing of urine samples for drugs of abuse and subsequent shipment of the sample, more particularly, to such a test kit having a cup-like container and a test card for indicating visually the presence of particular drugs of abuse.

BACKGROUND ART

The increased availability and use of drugs of abuse by the general population has caused employers, governmental agencies, sports groups and other organizations to utilize drug screening both as a condition of employment and in order to maintain safety in the work place. Typical drug screening tests are performed for the purpose of quickly identifying on a qualitative basis the presence of drugs in a body fluid which

may be urine. A complete analysis of the sample may then be carried out in a laboratory only if the preliminary screening results are positive. More and more such drug screenings are taking place on site or the work place and are generally carried out by testing personnel who are generally not technically trained, such as laboratory technicians. It is thus important that the drug screening procedure is simple but yet reliable. Further, the test apparatus must be such so as to enable the testing personnel to avoid all contact with the fluid specimen which is being tested.

Various forms of devices have been proposed for the collection and taking of body fluids, such as urine, which have proved to be cumbersome in operation since they involve a number of separate steps. Initially, the sample was collected and several additional steps were then required to transfer the urine sample to an analysis device. This multiple step procedure required the manual handling of the specimen through various devices and the use of such transfer devices inevitably caused spills which may result in contamination to the tester and surroundings. In addition, nontechnical personnel who perform the screening tests on urine samples objected to coming into any kind of contact with the urine sample and even the handling of the sample itself.

Many of the known testing devices were rather complex in that they included a container for the specimen, and,

subsequently it was necessary to transfer the specimen or at least a portion thereof to another compartment of the container in order to perform the test. This transfer of the specimen required vigorous shaking of the container or turning the container upside down in order to cause the flow of the specimen into a test compartment. It was therefore necessary to make the containers leak proof under such condition and the results was a complicated and expensive container structure.

Further, the containers incorporated the structure by means of which reagent strips were mounted in a test compartment of the container and which structure also enabled the fluid sample to flow into the test compartment into contact with the reagent strips. Such a mounting of the reagent strips further resulted in complicating the structure of the container since it was also necessary that provision be made to view the reagent strips from outside of the container. This was generally achieved by providing a transparent window or some other mounting of the reagent strips so as to be visible to testing personnel.

DISCLOSURE OF INVENTION

It is therefore the principal object of the present invention to provide a simplified and inexpensive device for the collection and testing of body fluid samples, particularly urine, for drugs of abuse and subsequent shipment of the sample.

It is an additional object of the present invention to provide such a device which includes a closed container for retaining a urine sample having such a closure structure that test card having a plurality of test strips thereon may be introduced into the container such that the test strips contact the urine sample.

It is a further object of the present invention to provide a test card having a plurality of immunoassay test strips thereon with each strip being responsive to a particular drug of abuse and having a visual endpoint to indicate the presence or absence of a particular drug.

The objects of the present invention are achieved and the disadvantages of the prior art are eliminated by the drug abuse test device according to the present invention which may comprise a cup-like transparent container for retaining a urine sample to be tested. The open top of the container has a closure cover or cap and there is a diametrical slit in the cap. The slit is of such a size to accommodate a test care which as a plurality of immunoassay test strips mounted thereon in parallel on one side and each test strip is responsive to a particular drug of abuse. The test card is insertable through the slit so as to have one end immersed in the urine sample to a predetermined depth whereby the visual results of each test strip can be seen through the transparent wall of the container without removing the test card from the container so as to

indicate the presence or absence of a particular drug of abuse in the urine sample. If the sample should test "positive" to indicate the presence of a drug in the urine, it is then necessary to send the sample to a certified laboratory for confirmatory testing. For this purpose, a second closure cap which is solid, i.e., not slit, is provided which may be threaded onto the open end of the cup-like container. The test card is removed from the container, the solid closure cap is threaded on to close the container and the container is then ready for shipment to a laboratory.

As described above, the test kit includes a drug abuse test device for collecting and testing a urine sample. This test device comprises a cup-like container having a transparent wall and having an open top upon which is threaded a closure cover provided with a slit therein to receive a test card. A solid second closure cap which threads over the outer end of the cup-like container is provided to seal the container to permit the safe shipment of a fluid sample therein.

The test kit also includes a screen test card for drugs of abuse which may comprise a thin flat member having the size and shape of a business card. A plurality of immunoassay test strips are fastened side by side in parallel on one side of the test card within the outline of the card. Each test strip is reactive to provide a visual indication in response to a particular drug of abuse. This test card thus provides for the

simultaneous detection of multiple analytes.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the present invention will be apparent upon reference to the accompanying description when taken in conjunction with the following drawings, which are exemplary, wherein;

Fig. 1 is a perspective view of the drug abuse test kit according to the present invention generally showing the container, the test card partially inserted to the testing position in the container through a slit in the cover;

Fig. 2 is an exploded perspective view of the container according to the present invention for collecting and testing a fluid sample and generally showing the container, a cover having a slit covered with a removable adhesive seal and a second solid closure cap;

Fig. 3 is a plan view of the test side of a test card according to the present invention;

Fig. 4 is a plan view of the reverse side of the test card shown in Fig. 3;

Fig. 5 is an end elevational view of the test card shown in Fig. 3;

Fig. 6 is a sectional view taken along the lines VI-VI of Fig. 3;

Fig. 7 is a plan view of the opened two piece test card before it is folded over to form the test card shown in Figs.

3-6;

Fig. 8 is a plan view of the test side of a modification of the test card;

Fig. 9 is a plan view of another modification of the test card;

Fig. 10 is a sectional view taken along the lines IX-IX of Fig. 8;

Fig. 11 is a plan view of the test side of a further modification of the test card;

Fig. 12 is a plan view of the center ply of the test card of Fig. 11 and showing a test strip in a slot thereof;

Fig. 13 is a plan view of the reverse side of the test card of Fig. 11;

Fig. 14 is a sectional view taken along the lines XIII-XIII of Fig. 11.

MODES FOR CARRYING OUT THE INVENTION

As may be seen in Figs. 1 and 2, a drug abuse test kit according to the present invention is indicated generally at 10 and comprises a cup-like transparent test container or cup 11 having a cylindrical side wall 12, a closed bottom 13 and an open top 14. The cylindrical wall 12 may have a slight taper or be straight.

The open end 14 of the test cup 11 is provided with external threads 21 upon which is seated an outer closure cover or cap 22 provided with corresponding internal threads which

are not shown in the drawing. The cover 22 has a circular top surface 23 from the periphery of which depends a cylindrical wall 24 on the inner surface of which there are provided internal threads. The cover surface 23 has a diametrical slit 19 therein shaped to accommodate a test card as will be presently described. There is also provided a solid cover or cap 15 which is similar in size and shape to the cover 22 but is solid or unslit so that the covers 15 and 22 may be interchangeably mounted on the open end 14 of the test cup 11. During shipment, the cover 15 is generally fitted on the bottom of the test cup. A temperature strip 16 is mounted on the bottom side wall of the test cup so as to be responsive to the temperature of the test sample within a test cup.

A test card 25 which will indicate the presence or absence of any one of 5 different drugs of abuse is shown in Fig. 1 inserted within the slit 19 in the closure cap 22 and in further detail in Figs. 3-6. The test card is of the multiple drug type in that test strips for five different drugs of abuse are mounted on the test card. The test strips 26-30 are spaced apart in parallel on a test side 31 of the test card. These test strips indicate the presence or absence of the following specific drugs of abuse: PCP, cocaine, amphetamines (AMP), marijuana (THC) and opiates. Test strips 26-30 may be of the type as made by Bionike of South San Francisco, California, Phamatech of San Diego, California and Arista Biological of

Bethlehem, Pennsylvania. Such test strips are characterized as immunoassay strips and employ colloidal gold chemistry. Each test strip is submerged up to a maximum line indicated at 32 and the results of the test are read in a test area indicated at 33. A blue line in the test area indicates positive or the presence of the particular drug in the test sample.

The test strips are actually recessed in slots in the card so that portions of the test strips project above the test surface 31 of the card as may be seen in Fig. 5. The test card may be formed of two plys 34 and 35 as may be seen in Fig. 7 and these plys in turn are formed from a single strip having a bend or fold 36. The ply 35 is formed with a plurality of die cut slots 37 which are shaped and sized to receive each of the test strips. Thus, in the fabrication of a test card, the two portions 34 and 35 are folded over at end 36 and are adhered together. The test strips are then placed into the slots as shown in Fig. 6 and each of the test strips is adhered to the surface of the first portion 34 upon which the second portion 35 has been folded.

It is also within the scope of this invention to make this test card of two separate or individual plys 34 and 35 which are then adhered together and the strips are fixed in the slots as described above.

In order to conduct a drug abuse test utilizing the test card according to the present invention a person being tested

must first provide a urine specimen into the transparent test cup 11. The quantity of specimen provided must be such as to permit insertion of the test card up to about the maximum line indicated at 32. It is also possible to provide fill lines on the wall surface of the test container.

The test cup with a sufficient quantity of test specimen therein is then closed by threading the cap 22 on the top of the test cup. The cap 22 is provided with a readily removable adhesive sealing strip 18 which is placed over the slit 19. Thus, when the container with the test specimen is brought to the person conducting the test, the protective strip 18 is removed and the multiple drug test card 25 inserted into the slit so that the bottom of the test card rests upon the bottom of the test cup. Fifteen (15) ml. of specimen will ensure that the specimen does not go above the maximum fill line 32. The test card then remains in place for at least three minutes and the results of the test can be read on each individual test strip through the transparent wall of the container. Thus, if a blue line appears on any one of the test strips, this indicates positive and the presence of that particular drug of abuse in the test specimen. If no such blue line appears then the absence of any of the five drugs of abuse from the specimen is indicated. With such a negative result, the urine sample and the container are discarded.

However, when the results of the test are positive, it is

preferable to send the specimen to a certified laboratory for a confirmatory analysis by more specific methods of testing such as gas chromatography or mass spectrometry. In order to ship the sample in the container, the closure 22 is removed and the solid cover 15 is threaded down tightly upon the open end of the container.

In Fig. 8, there is shown at 40 a modification of the test card as described above and is similarly constructed with two plys but is also provided with a third or top ply 41 which is adhered to the two plys and covers the test strips. The third play 41 is provided with an opening 42 through which the test and control lines may be seen. In this modification, those portions of the plys below the maximum fill line 32 are removed such that the test strips 26-30 project beyond a bottom end 43 of the shortened test card. Otherwise, this test card functions in precisely the same manner as described above.

A modification of the test card is shown at 44 in Fig. 9. In this modification, the test strips are covered but the pertinent test and sample portions of the test strips are exposed through openings. The test card 44 comprises a central ply 45 of styrene which has a thickness of 1.25 mm. corresponding to or slightly greater than the thickness of the test strips and slots are provided in the center ply to receive the test strips. The top and bottom faces of the central ply 45 are covered by a bottom ply 46 and a top ply 47 which may be

made from a single piece of material double scored at 48 and 49 so as to wrap around the central ply 45 in the manner as shown in Fig. 9. The top and bottom plys may be of a thin vinyl sheet or cardboard coated with plastic. The top ply 47 is provided with a plurality of test windows 50 through which the test results as indicated by the test strips can be seen. At the lower end of the card are provided sample openings 51 through which the liquid test specimen is able to contact the absorbent or sample portions of the test strips.

In Figs. 11-14 there is shown a modification of the test card 44 in which the card is made of three separate plys which are then laminated. The bottom and top plys 46 and 47 are made of a thin vinyl sheet having a thickness of 0.33 mm. and the center ply 45 is made of styrene having a thickness of about 1.25 mm. The top ply 47 similarly has the test openings or windows 50 and the sample openings 51 and the bottom ply 46 is solid as shown.

The central ply 45 is provided with a plurality of longitudinally extending slots 52 and a test strip 53 is seated in each of these slots as shown. The test strip generally has a length less than that of the slot 52. In this embodiment, only a single test strip for THC (marijuana) is shown. While this embodiment of the test card has provision for five test strips, it is to be understood that the card can be made in the same manner with less than five strips and even a single strip

if so desired. In such a modification, the windows 50 and 51 for the omitted strips are usually solid.

Each of the test strips 26-30 is a one-step immunoassay in which a specially labeled drug, (drug conjugate) competes with drug which may be present in the sample for the limited number of binding sites on an antibody. The test strip consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody complex moves with the urine sample by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the test area. The formation of a visible line in the test area occurs when the test is negative for the drug. When a drug is present in the urine sample, the drug or its metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the label antibody to the drug conjugate. An absence of a color line or band in the test area is indicative of a positive result. A control band or line comprised of a different antibody/antigen reaction is present on the membrane strip. The control line is not influenced by the presence or absence of drug in the urine and therefore

INDUSTRIAL APPLICABILITY

Thus it can be seen that the present invention discloses a novel and improved drug abuse test kit which comprises a container for the fluid specimen being tested and a multiple drug test card which is inserted in the specimen within the container and the visual results of the test are read on the test card through the transparent wall of the container. The test card thus comprises a number of individual test strips of the immunoassay type and each strip is responsive or indicative to a particular drug of abuse. The test card may be made of plastic coated cardboard or thin sheets of plastic which are laminated together. This drug abuse test kit enables one to obtain rapidly a visual, qualitative result which is very advantageous for forensic purposes but is not limited to such purposes.

It will be understood that this invention is susceptible to modification in order to adapt it to different usages and conditions, and accordingly, it is desired to comprehend such modifications within this invention as may fall within the scope of the appended claims.

should be present in all reactions.

In summary, if a single band appears in the control zone and no band appears in the test zone then the results are "positive" which indicates that that particular drug is present above a predetermined level which is usually around 50ng/ml. If two color bands appear, one in the control region and the other in the test region then the test results are "negative" which indicates that the level of that particular drug is below the predetermined detection of sensitivity.

In the event that there are no distinct color bands visible in both the test zone and the control zone or if there is a visible band in the test zone but not in the control zone, then the result is invalid and retesting of the specimen is recommended with another test card.

The test card can also be used as a carrier or delivery system for a biological detection or monitor device by replacing the drug test strips with strips treated with suitable chemicals so as to be responsive to different and selected biological warfare agents. The strips would then function similarly to drug abuse strips to provide a visual indication of the presence in a predetermined quantity of a specific biological warfare agent or the absence of such an agent.

What is claimed is:

1. A drug abuse test kit comprising a cup-like transparent container having an open top end for retaining a urine sample to be tested, a closure cap seated upon said open top end and having a diametrically disposed slit therein, a test card having a plurality of visual indication test strips disposed in parallel on one side thereof and each strip being responsive to a particular drug of abuse, said test card having such a width and thickness that one end of said test card is insertable through said slit to be immersed in a urine sample retained therein to a predetermined depth, the results of each test strip can be seen through the transparent wall of the container without removing the test card from the container to indicate the presence or absence of a particular drug of abuse in said urine sample.

2. A drug abuse test kit as claimed in claim 1 and further comprising a solid second closure cap positionable over the open end of the container in place of said closure cap with a slit.

3. A drug abuse test device for collecting and testing a urine sample comprising a cup-like transparent container having an open top end for retaining a urine sample to be tested, a first closure cap seated upon said open top end and having a diametrically disposed slit therein, and a solid second closure

cap positionable over said open top end in place of said first closure cap to seal the container so as to permit transportation of a fluid sample therein without leakage.

4. A drug abuse test device as claimed in claim 3 and further comprising a protective adhesive strip over said slit which is removable prior to testing the specimen within the container.

5. A multiple drug test card for drugs of abuse comprising a thin flat member having the size and shape of a business card and having a first side, a plurality of immunoassay test strips with visual endpoints to indicate presence or absence of a drug adhered side-by-side in parallel on said first side within the outline of said flat member and having at least portions thereof exposed, each test strip indicating the presence or absence of a particular drug of abuse.

6. A multiple drug test card as claimed in claim 5 wherein said test strips are each recessed in said first side.

7. A multiple drug test card as claimed in claim 5 wherein said test strips are disposed parallel to the longer dimension of said flat member.

8. A multiple drug test card as claimed in claim 5 wherein there are a plurality of spaced parallel slots on said

first side and said test strips are seated in said slots.

9. A multiple drug test card as claimed in claim 5 wherein exposed portions of said test strips are recessed inwardly of said first side surface.

10. A multiple drug test card as claimed in claim 5 wherein said thin flat member comprises three laminated sheets, one of said sheets defining a backing sheet, a second of said sheets having a plurality of parallel slots therein to receive said test strips, and a third of said sheets having spaced parallel slots therein corresponding with said test strips, said sheets being adhered together such that said first and third sheets sandwich the second sheet there between.

11. A multiple drug test card as claimed in claim 5 wherein said thin flat member has front and rear surfaces and a thickness substantially equal to the thickness of said test strips, there being slots in said thin flat member to receive said test strips therein, a second thin flat member adhered to said rear surface of said thin flat member, a third thin flat member adhered to the front surface of said thin flat member, there being openings in said third thin flat member to expose the sample and test portions of each of said test strips.

12. A multiple drug test card as claimed in claim 5 wherein said second and third thin flat members comprise a

single sheet of material having a fold therein and folded around said first thin flat member.

13. A multiple drug test card as claimed in claim 11 wherein said second and third thin flat members are thinner than said first thin flat member.

14. A multiple drug test card as claimed in claim 5 wherein said test card has a bottom end and said test strips have ends projecting outwardly of said bottom end.

15. A multiple drug test card as claimed in claim 14 and further comprising a cover sheet covering said first side of said thin flat member and said test strips, there being an opening in said cover sheet to expose portions of said test strips.

ABSTRACT

A drug abuse test kit has a transparent cup-like container for retaining a fluid sample to be tested and the open top end of the container is closed by a closure cap seated upon the open end. There is a slit in the closure cap to receive a multiple drug test card having a plurality of immunoassay test strips thereon with visual endpoints to indicate presence or absence of a particular drug. The container is provided with a second cover which is solid and unslit to close and seal the container when a sample therein is to be transported.

FIG. 1

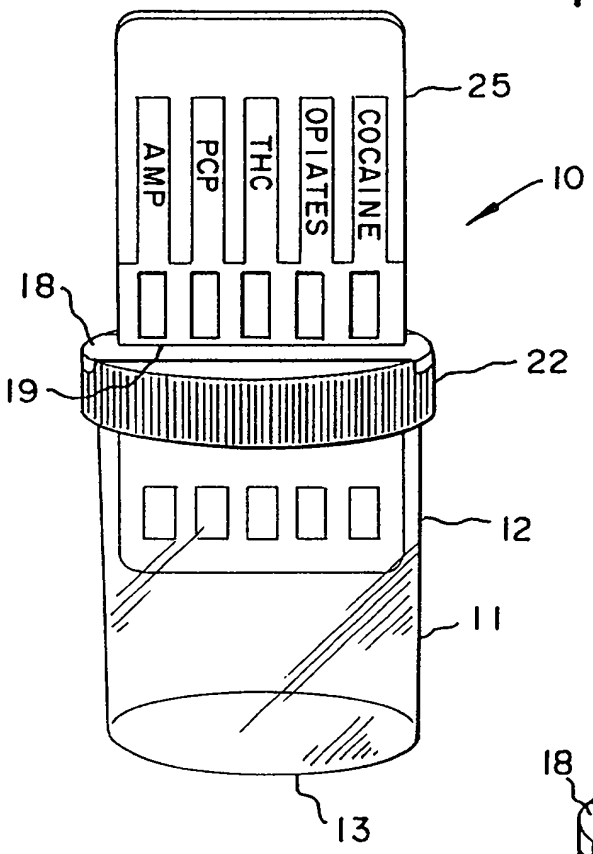


FIG. 2

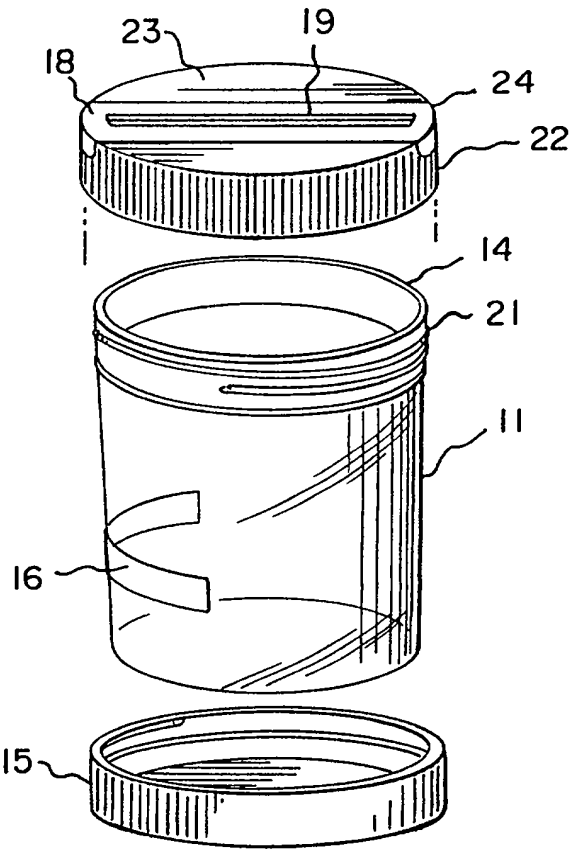
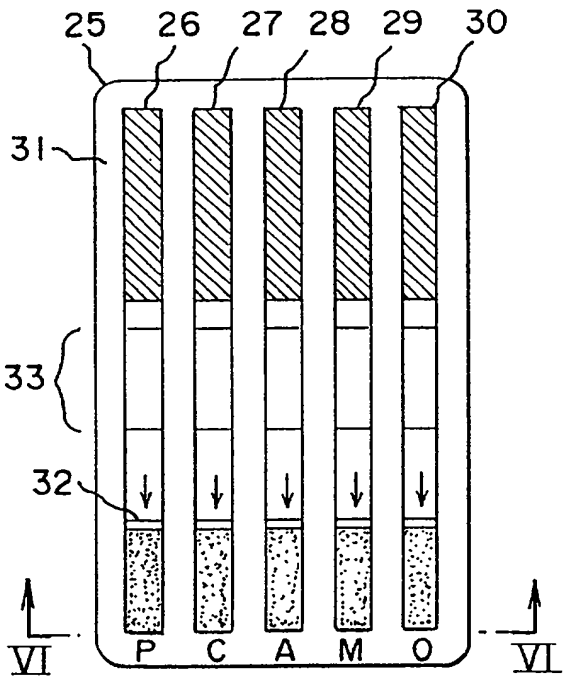


FIG. 3



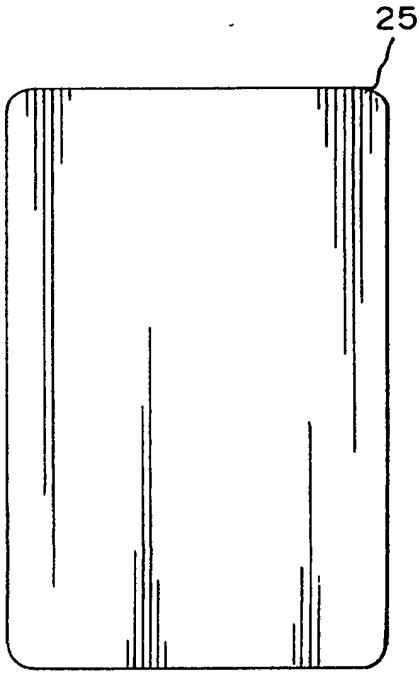


FIG. 5

FIG. 4

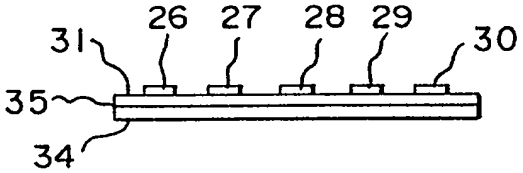


FIG. 6

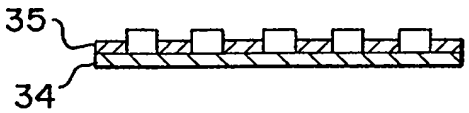


FIG. 7

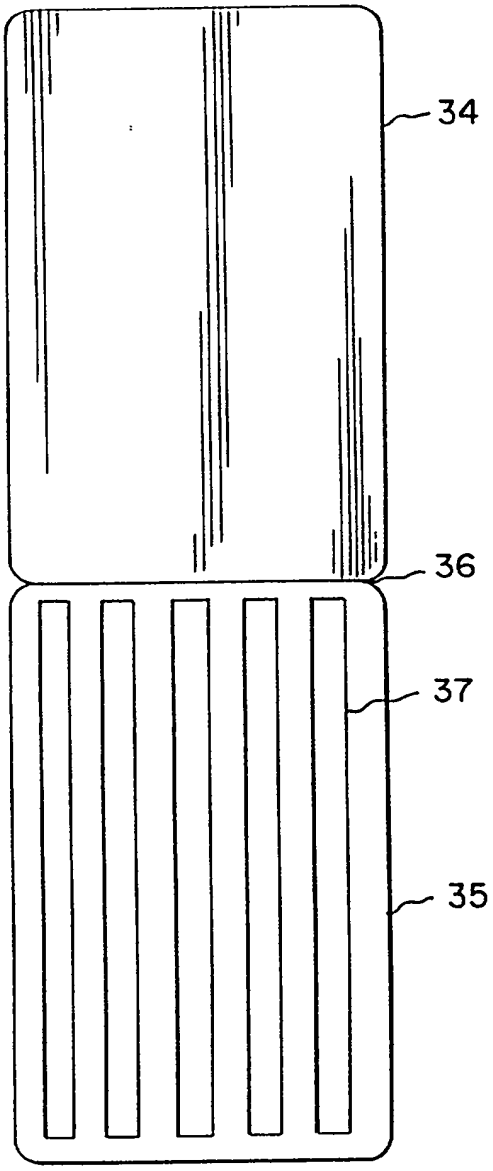


FIG. 8

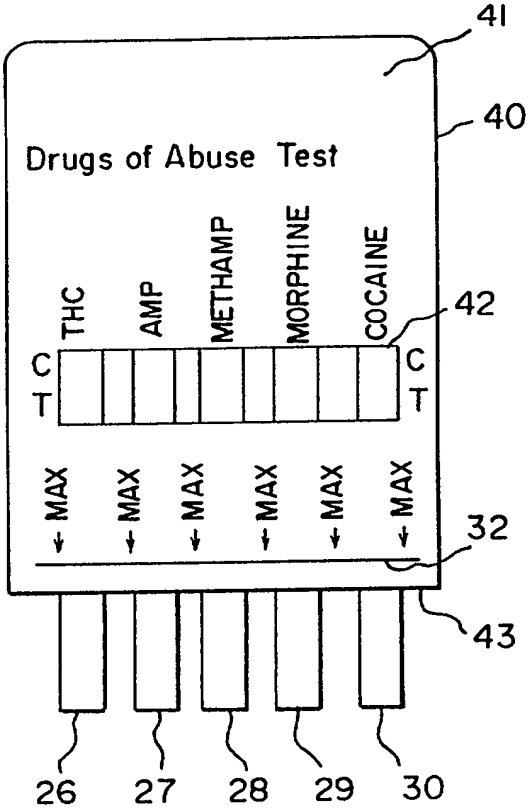


FIG. 9

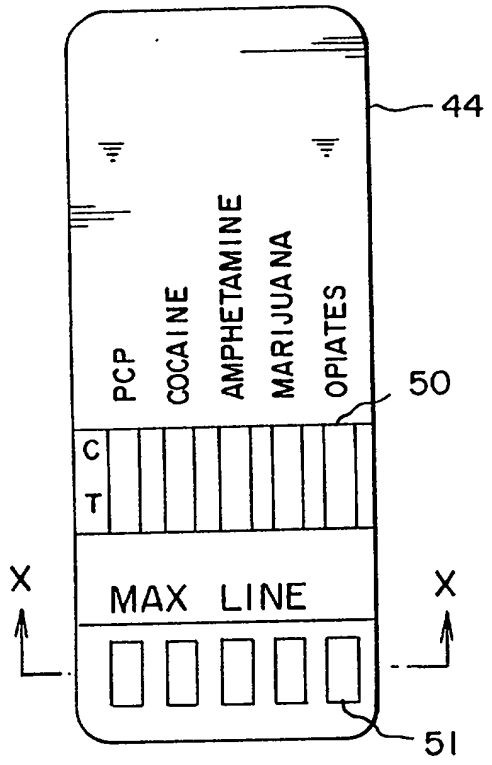


FIG. 11

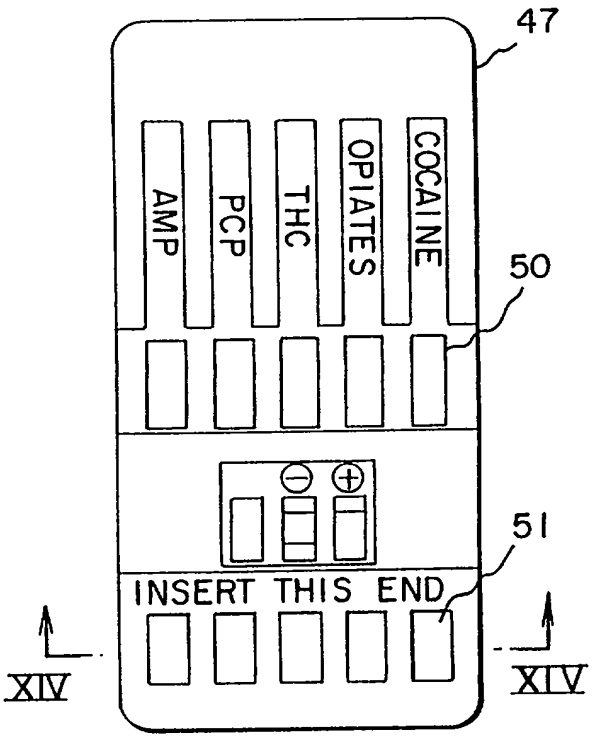
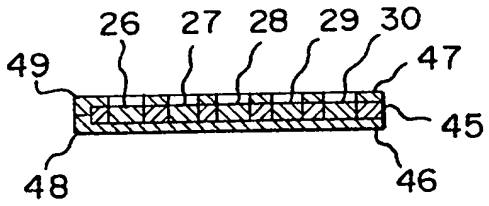


FIG. 10



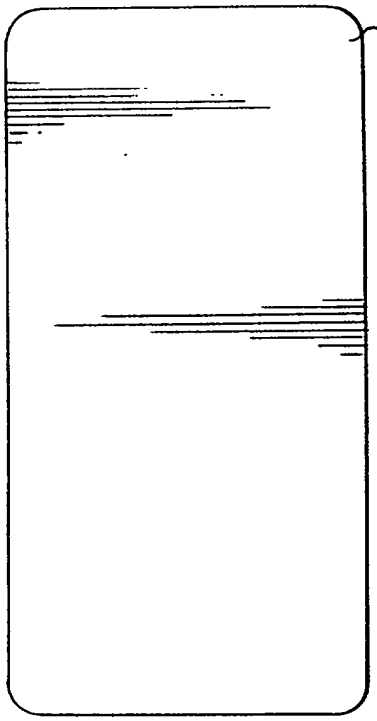


FIG. 13

FIG. 12

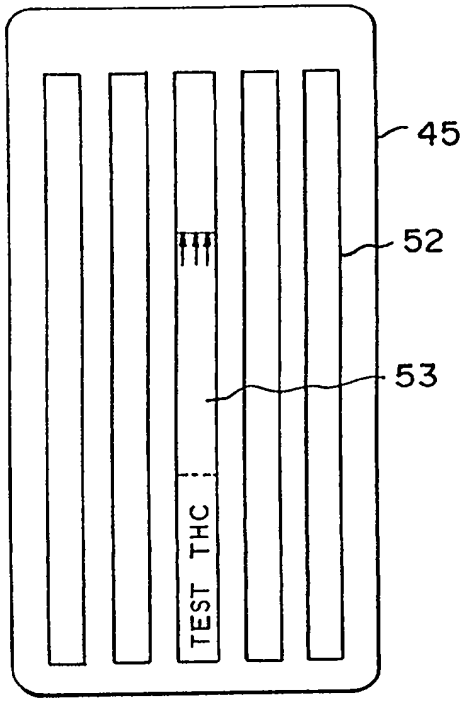
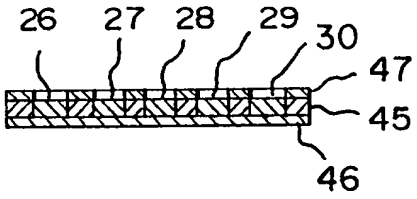


FIG. 14



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of Stan Cipkowski

Serial No.: Attorney's

Filed: Docket No. 3000

For: DEVICE FOR THE COLLECTION, TESTING AND SHIPMENT OF BODY FLUID SAMPLES

VERIFIED DECLARATION CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27 (c)) - SMALL BUSINESS CONCERN

I hereby declare that I am an official of the small business concern empowered to act on behalf of the concern identified below: American Bio Medica Corporation.
Ancramdale, New York

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.3-18 and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under section 41 (a) and (b) of Title 35 United States Code in that the number of employees of the concern, including this of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party of parties controls or has the power to control both.

I hereby declare that all rights under contract or law have been conveyed to an remain with the small business concern identified above with regard to the invention, entitled

by inventor
described in the specification filed herewith.

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28 (b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Stan Cipkowski
TITLE OF PERSON SIGNING President
ADDRESS OF PERSON SIGNING 102 Simons Road
Ancramdale, New York 12503

SIGNATURE _____ DATE Oct. 28, 1997

Attorney's Docket No. 3000

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (*check one applicable item below*)

- ☐ original
- ☐ design
- ☐ supplemental

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check next item; check appropriate one of last three items.

- ☒ national stage of PCT

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

- ☐ divisional
- ☐ continuation
- ☐ continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

DEVICE FOR THE COLLECTION, TESTING AND SHIPMENT OF BODY FLUID SAMPLES

SPECIFICATION IDENTIFICATION

the specification of which: *(complete (a), (b) or (c))*

(a) ☒ is attached hereto.

(b) ☐ was filed on _____ as ☐ Serial No. 0 /_____ or ☐ Express Mail No., *as Serial No not yet known* _____ and was amended on _____ (*if applicable*)

NOTE: Amendments filed after the original papers are deposited with the PTO which contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 CFR 1.67.

(c) ☒ was described and claimed in PCT International Application No. PCT/US97/03347 filed on March 11, 1997 and as amended under PCT Article 19 on _____ (*if any*)

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information

☒ which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

(also check the following items, if desired)

☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ In compliance with this duty there is attached an information disclosure statement in accordance with 37 CFR 1.98.

PRIORITY CLAIM (35 U.S.C. § 119)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ☐ no such applications have been filed.

(e) ☒ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

A. PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, **month**, year)	PRIORITY CLAIMED UNDER 37 USC 119
PCT	PCT/US97/03347	11 March 1997	☒ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐
			☐ YES NO ☐

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

NOTE: *If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CIP APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.*

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. (*List name and registration number*)

Edmund M. Jaskiewicz Reg No. 17875
1730 M Street NW Ste. 400
Washington, D.C. 20036

(check the following item, if applicable)

☐ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

Edmund M. Jaskiewicz
at above address

DIRECT TELEPHONE CALLS TO:
(*Name and telephone number*)

Edmund Jaskiewicz
(202) 296-2900

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE: Carfefully indicate the family (or last) name as it should appear on the filing receipt and all other documents.

1 OD

Full name of sole or first inventor

Stan (GIVEN NAME) _____ (MIDDLE INITIAL OR NAME) Cipkowski (FAMILY (OR LAST NAME)

Inventor's signature _____

Date October 28, 1997 Country of Citizenship USA

Residence Ancramdale, New York NY

Post Office Address 102 Simons Road
Ancramdale, NY 12503

Full name of second joint inventor, if any

_____ (GIVEN NAME) _____ (MIDDLE INITIAL OR NAME) _____ (FAMILY (OR LAST NAME)

Inventor's signature _____

Date _____ Country of Citizenship _____

Residence _____

Post Office Address _____

Full name of third joint inventor, if any

_____ (GIVEN NAME) _____ (MIDDLE INITIAL OR NAME) _____ (FAMILY (OR LAST NAME)

Inventor's signature _____

Date _____ Country of Citizenship _____

Residence _____

Post Office Address _____

CHECK PROPER BOX(ES) FOR ANY OF THE FOLLOWING ADDED PAGE(S) WHICH FORM A PART OF THIS DECLARATION

☐ Signature for third and subsequent joint inventors. *Number of pages added* _____.

* * *

☐ Signature by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____

* * *

☐ Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____.

* * *

☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (CIP) application.

☐ Number of pages added _____

* * *

☐ Authorization of attorney(s) to accept and follow instructions from representative

* * *

If no further pages form a part of this Declaration then end this Declaration with this page and check the following item

☒ This declaration ends with this page

United States Patent & Trademark Office

Office of Initial Patent Examination -- Scanning Division

Application deficiencies found during scanning:

1. Application papers are not suitable for scanning and are not in compliance with 37 CFR 1.52 because:
   - ☐ All sheets must be the same size and either A4 (21 cm x 29.7 cm) or 8-1/2"x 11". Pages _____ do not meet these requirements.
   - ☐ Papers are not flexible, strong, smooth, non-shiny, durable, and white.
   - ☐ Papers are not typewritten or mechanically printed in permanent ink on one side.
   - ☐ Papers contain improper margins. Each sheet must have a left margin of at least 2.5 cm (1") and top, bottom and right margins of at least 2.0 cm (3/4").
   - ☐ Papers contain hand lettering.

2. Drawings are not in compliance and were not scanned because:
   - ☐ The drawings or copy of drawings are not suitable for electronic reproduction.
   - ☐ All drawings sheets are not the same size. Pages must be either A4 (21 cm x 29.7 cm) or 8-1/2" x 11".
   - ☐ Each sheet must include a top and left margin of at least 2.5 cm (1"), a right margin of at least 1.5 cm (9/16") and a bottom margin of at least 1.0 cm (3/8").

3. Page(s)_____ are not of sufficient clarity, contrast and quality for electronic reproduction.

4. Page(s) 3 of Declaration are missing.

5. OTHER:_____